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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,694	05/20/2004	Matthias Mitschke	P04,0210	7645

7590

01/11/2006

SCHIFF HARDIN LLP

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EXAMINER

HO, ALLEN C

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

EK

Office Action Summary	Application No. 10/849,694	Applicant(s) MITSCHKE ET AL.	
	Examiner Allen C. Ho	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07092004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **14a, 14b**.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: S1-S5.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:

Page 9, line 24, "divided" should be replaced by --avoided--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 recite "marker-less navigation. The applicants disclosed that the determination of the C-arm position and the intraoperative 3D images is based on a tool plate (TP) mounted on the C-arm, which is detected by a navigation system (S). Since the tool plate itself is considered a marker, it is unclear what is considered to be marker-less navigation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Simon *et al.* (U. S. Patent No. 6,470,207 B1).

With regard to claim 5, Simon *et al.* disclosed an x-ray system comprising: a C-arm (103) on which an x-ray source (104) and a radiation detector (105) are mounted; and a control and processing unit (115). Note: The language "for" in lines 7, 11, 13, and 16 is interpreted to be intended use. A recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seeley *et al.* (U. S. Patent No. 6,484,049 B1) in view of Dekel (U. S. Pub. No. 2002/0172328 A1).

With regard to claims 1, 2, and 4, Seeley *et al.* disclosed a method for marker-less navigation of a medical instrument comprising the steps of: during a medical interventional procedure involving interaction of a medical instrument with a subject, intraoperatively acquiring a 3D image of the subject using a C-arm x-ray system (column 14, lines 57-66); bringing the medical instrument into registration with the 3D image (column 9, lines 26-48); bringing the 3D image into registration with respect to a pre-existing preoperative 3D image using an image-based registration, and thereby obtaining a second registration matrix (column 14, line 66 - column 15, line 6); and navigate the medical instrument in the preoperative 3D image.

However, Seeley *et al.* failed to teach bringing the medical instrument into registration with the 3D image by obtaining a first registration matrix.

Dekel disclosed a method that brings a medical instrument into registration with intraoperatively acquired images, and thereby obtaining a first registration matrix (paragraph [0018] - [0019]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to obtain a first registration matrix, since a person would be motivated to superimpose the medical instrument into the 3D image by calculating the coordinates of the medical instrument in the frame of the 3D image.

With regard to claim 3, Seeley *et al.* and Dekel disclosed a method as claimed in claim 1, further comprising the step of taking deformation of the C-arm x-rays system into account for determining the second registration matrix (column 7, line 64 - column 9, line 3).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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11. Claims 1, 2, 4, and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/850,499 in view of Dekel (U. S. Pub. No. 2002/0172328 A1).

With regard to claims 1 and 4, claim 1 of copending Application No. 10/850,499 claims a method comprising the steps of: intraoperatively acquiring a 3D image of a subject using a C-arm x-ray system; bring the 3D image into registration with respect to a pre-existing preoperative 3D image using an image-based registration, and thereby obtaining a second registration matrix (matching matrix).

However, claim 1 of copending Application No. 10/850,499 fails to claim the step of bringing a medical instrument into registration with the 3D image, and thereby obtaining a first registration matrix.

Dekel disclosed a method that brings a medical instrument into registration with intraoperatively acquired images, and thereby obtaining a registration matrix (paragraph [0018] - [0019]). Dekel taught that surgical procedures often require a surgeon to navigate medical instruments without being able to directly visualize their precise location within the body. (paragraph [0022]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to bring a medical instrument into registration with the 3D image, since a person would be motivated to navigate the medical instrument with respect to an intraoperatively obtained 3D image in real time.

With regard to claim 2, claim 1 of copending Application No. 10/850,499 and Dekel claim a method as claimed in claim 1, comprising obtaining the first registration matrix by marker-free registration (Dekel, paragraph [0017]).

With regard to claim 5, claim 1 of copending Application No. 10/850,499 claims an x-ray system comprising: a C-arm on which an x-ray source and a radiation detector are mounted; and a control and processing unit that acquires an intraoperative 3D image of the subject, and registers the 3D image with respect to a pre-existing preoperative 3D image.

However, claim 1 of copending Application No. 10/850,499 fails to claim a control and processing unit that registers a medical instrument with respect to the intraoperative 3D image and obtains a first registration matrix.

Dekel disclosed a method that brings a medical instrument into registration with intraoperatively acquired images, and thereby obtaining a registration matrix (paragraph [0018] - [0019]). Dekel taught that surgical procedures often require a surgeon to navigate medical instruments without being able to directly visualize their precise location within the body. (paragraph [0022]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to bring a medical instrument into registration with the 3D image, since a person would be motivated to navigate the medical instrument with respect to an intraoperatively obtained 3D image in real time.

This is a provisional obviousness-type double patenting rejection.

12. Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/850,499 and

Dekel (U. S. Pub. No. 2002/0172328 A1), and further in view of Seeley *et al.* (U. S. Patent No. 6,484,049 B1).

With regard to claim 3, claim 1 of copending Application No. 10/850,499 and Dekel (U. S. Pub. No. 2002/0172328 A1) claim a method as claimed in claim 1.

However, claim 1 of copending Application No. 10/850,499 and Dekel (U. S. Pub. No. 2002/0172328 A1) fail to claim the step of taking C-arm deformation into account for determining the second registration matrix.

Seeley *et al.* disclosed a method that takes deformation of the C-arm x-rays system into account for determining a registration matrix (column 7, line 64 - column 9, line 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to take the deformation into account for determining the second registration matrix, since a person would be motivated to accurately map the 3D image onto the preoperative 3D image.

This is a provisional obviousness-type double patenting rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- (1) Schweikard *et al.* (U. S. Patent No. 6,788,062 B2) disclosed a method that register CT-fluoroscopic image with an MR image.
- (2) Zheng *et al.* (U. S. Pub. No. 2004/0111024 A1) disclosed a method for establishing a three-dimensional representation of a bone from image data.

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(3) Verard *et al.* (U. S. Pub. No. 2004/0097805 A1) disclosed a navigation system for cardiac therapies.

(4) Yanof *et al.* (U. S. Patent No. 6,149,592) disclosed integrated fluoroscopic projection image data, volumetric image data, and surgical device position data.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allen C. Ho whose telephone number is (571) 272-2491. The examiner can normally be reached on Monday - Friday from 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached at (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Allen C. Ho
Primary Examiner
Art Unit 2882

06 January 2006